OMS OSMOTET 500MG/G
PREMIX POWDER

Composition
Each gm contain:
Oxytetracycline Hydrochloride……500mg

Product Description
Creamy yellowish powder.

Pharmacodynamics
The oxytetracycline links reversibly to the ribosomal subunit 30S receptors, this leading to a blockage of the union between aminoacyl-tRNA to the site corresponding to the mRNA-ribosome complex messenger.
It results in an inhibition of the protein synthesis and inhibits bacterial growth. The mainly bacteriostatic activity of oxytetracycline involves uptake of the substance into the bacterial cell which occurs by both passive and active diffusions. The main mechanism of resistance is due to the possible presence of a R factor responsible for a decrease in the active transport of oxytetracycline.

Oxytetracycline is a broad-spectrum antibiotic. It is mainly active against Gram-positive and Gram negative bacteria, aerobic and anaerobic, as well as against mycoplasma, the Chlamydia and Rickettsiae.

Acquired resistance to oxytetracycline has been reported. This resistance is usually of plasmid origin. Cross-resistance to other tetracyclines is possible. The prolonged or repeated use of oxytetracycline as well as continuous treatment with low doses of oxytetracycline may also cause increased resistance to other antibiotics due to potential co-resistance with other antimicrobials

Four resistance mechanisms acquired by microorganisms against tetracyclines in general have been reported: decreased accumulation of tetracyclines (decreased permeability of the bacterial cell wall and active efflux), protein protection of the bacterial ribosome, enzymatic inactivation of the antibiotic and rRNA mutations (preventing the tetracycline binding ribosome).

Pharmacokinetics
The oxytetracycline diffuses throughout the body, the highest concentrations have been found in the kidneys, liver, spleen and lungs. The oxytetracycline crosses the placental barrier.

Oxytetracycline is excreted unchanged mainly via urine. It is also excreted via bile but a high proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

Indication
Chickens:
For reduction of mortality due to air sacculitis (air-sac infection) caused by *E.coli* susceptible to oxytetracycline

For control of chronic respiratory disease (CRD) and air sac infections caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.

For control of infectious synovitis caused by *Mycoplasma synoviae*, control of fowl cholera caused by *Pasteurella multocida* sensitive to oxytetracycline.

Swine:
For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline

For breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.

Mode of Administration
Orally. Mixed into feed.

Recommended Dosage
To be administered orally via the feed.

Chickens
For reduction of mortality due to air sacculitis (air-sac infection) caused by *E.coli* susceptible to oxytetracycline: 500 grams Oxytetracycline (1.08 kg OMS OSMOTET 500MG/G PREMIX POWDER) per ton of feed. Feed continuously for 5 days.

For control of chronic respiratory disease (CRD) and air sac infections caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline: 400 grams Oxytetracycline (0.86 kg OMS OSMOTET 500MG/G PREMIX POWDER) per ton of feed. Feed continuously for 7 to 14 days.

For control of infectious synovitis caused by *Mycoplasma synoviae*, control of fowl cholera caused by *Pasteurella multocida* sensitive to oxytetracycline: 100 – 200 grams Oxytetracycline (0.22 kg – 0.43 kg OMS OSMOTET 500MG/G PREMIX POWDER) per ton of feed. Feed continuously for 7 to 14 days.

Swine
For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline: 10 miligrams Oxytetracycline (0.02 g OMS OSMOTET 500MG/G PREMIX POWDER) per pound of body weight. Feed continuously for 7 to 14 days.

For breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline: 10 miligrams Oxytetracycline (0.02 g OMS OSMOTET 500MG/G PREMIX POWDER) per pound of body weight. Feed continuously for not more than 14 days.

Contraindications
Do not use in case of hypersensitivity to oxytetracycline or any other substance from tetracyclines group.

Do not use in cases of known oxytetracycline resistance.

Warnings and Precautions
Special warnings for each target species
None.

Special precautions for use in animals
Use of the product should be based on susceptibility testing of bacteria isolate from the animal. If not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to the oxytetracycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross-resistance.

Prolonged or repeated use should be avoided as these practises can enforce development and spread of the bacterial resistance. This is particularly likely in enterobacteria and *Salmonella spp.*, many of which are already resistant.
As eradication of the target pathogens may not be achieved, medication should be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

Extensive resistance to oxytetracycline has been recognised in porcine and poultry isolates of strains form *E. Coli*, *Salmonella spp*., *Campylobacter spp*., and *Enterococcus spp*. The product should only be used where culture and sensivity testing have demonstrated that it is likely to be effective.

Sick animals may have a reduced appetite and an altered drinking pattern and should, if necessary, be medicated parenterally.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Avoid inhaling dust when handling the product until complete solubilisation in water. Use in a well-ventilated area away from draughts.
Avoid contact with skin and eyes.

Personal protective equipment consisting of latex and nitrile gloves, eye protection dust mask (either a disposal half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143) and suitable protective clothing should be worn when handling the veterinary medicinal product. In case of accidental eye or skin contact, rinse the affected area with large amounts of clean water. If irritation occurs, seek medical advice immediately and show the label to the physician.
Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands and contaminated skin immediately after handling the product.
Do not smoke, eat or drink while handling the product.

Interactions with Other Medicaments
Divalent or trivalent cations (Mg, Fe, Al, Ca) may chelate with tetracyclines. The tetracylines should not be administered with antacids, gels containing aluminium, preparations containing vitamins or minerals as insoluble complexes will be formed, which decreases the absorption of the antibiotic.

Pregnancy and Lactation
Laboratory studies in animals have not produced any evidence of embryotoxicity or teratogenic effects.
In mammals, oxytetracycline pass the placental barrier, resulting in staining of teeth and slow foetal growth. Tetracyclines are found in breast milk.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Adverse Effects/Undesirable Effects
As for all other tetracyclines, side effects have been observed such as gastro-intestinal disorder and less frequently, allergic and photosensitivity reactions.

Overdose and Treatment
None known

Withdrawal Period(s)
Chicken: 24 hours
Swine: No withdrawal period is required

Storage condition
Store in a cool dry place, protected from light. Do not store above 30°C.
Keep out of reach of children/Jauhkan dari kanak-kanak.

Pack size(s)
Paper bag of 20kg

Product Registration Holder/ Manufacturer
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